REMARKS

Claims 1-40 are pending in this application.

In the Office Action dated January 20, 2004, item 4, the Office objected to claim 3 because it asserted that the term "wherein" was missing. Applicants have inserted this term before the term "the polymer" and respectfully request that the objection be withdrawn.

In item 6 of the Office Action mailed January 20, 2004, the Office rejected claims 1-31 and 33-40 under 35 U.S.C. § 102(b) as being anticipated by WO 95/13799 ("WO '799"). The Office asserted that this reference teaches microencapsulation of an active agent by coacervation. In addition, the Office rejected claim 32 under 35 U.S.C. § 103, in item 8, asserting that one of skill in the art would know to use a temperature of -4°C in the method taught in WO '799.

Independent claim 1 has been amended to add the term "wherein coacervation is performed with dynamic stirring." This term is supported by the references in the specification to "magnetic stirring," on page 13, lines 1-2, and to "mechanical stirring," on page 13, lines 7-8, lines 17-18, and lines 21-22. Such stirring implies dynamic stirring. Therefore, this amendment does not add new matter.

WO '799 does not disclose a process for microencapsulating an active principle by coacervation utilizing dynamic stirring. Instead, WO '799 teaches a process for "encapsulating active agents to form controlled-release microparticles through the use of *static mixers*." WO '799 at 1, lines 14-17 (emphasis added).

In fact, WO '799 teaches away from dynamic mixing techniques, such as stirring, agitating, and vibrating, by providing the drawbacks of these methods. WO '799 explains:

> Such dynamic mixing techniques have several drawbacks. For example, it is difficult to control the size of the resulting microparticles, or the distribution of sizes obtained. As a consequence, use of dynamic mixing also presents problems when preparing microparticles containing biological or pharmaceutical agents on a production or commercial sale. Particularly, production equipment includes a costly emulsion tank, including equipment to stir or agitate the fluids. One of the controlling factors for overall process time is the time required to form a homogeneous (uniform) emulsion. Increased batch sizes in larger tanks require a longer time to form the emulsion, resulting in longer overall production process time. Longer exposure times of the active agent to process solvents and to polymer solutions can lead to degradation or deactivation of the active agent. Scale-up to a production process from a laboratory emulsion process is particularly difficult for micorencapsulation of biological or pharmaceutical agents since, as the batch and tank size are increased, stir speeds and viscosities within the larger tank have to be empirically optimized by trial and error at each stage of the scale-up. Likewise, the phase separation technique is not easily converted into a process for producing commercial scale quantities of microparticles because processing parameters, i.e. rate of non-solvent addition, agitation conditions, and the viscosity of both the active agent/polymer solution and the non-solvent must be empirically optimized by trial and error at each stage of scale-up. Thus scale-up of conventional microencapsulation techniques is not only time consuming, but imprecise.

WO '799 at 6, line 16, to page 7, line 7. To overcome these problems, WO '799 teaches the use of static mixing. In contrast, the claimed invention provides a process that involves dynamic mixing and non-chlorinated solvents. Thus, neither claim 1, nor claims 2-40, which ultimately depend on claim 1, are anticipated or rendered obvious by

WO '799. Applicants respectfully request that the rejections under 35 U.S.C. § 102 and § 103 in light of WO '799 be withdrawn.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered, placing claims 1-40 in condition for allowance.

In addition, Applicants submit that the entry of the amendment and the remarks submitted herewith place the application in better form for appeal, should the Office dispute the patentability of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: July 19, 2004

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